## REMARKS

The present document is submitted in reply to the Office Action dated December 12, 2008 ("Office Action").

Initially, Applicants would like to thank the Examiner for granting a telephone interview with Applicants' counsel conducted on April 24, 2009. A part of the present document serves as a summary of the interview.

Applicants have amended claims 2, 10, 30, and 31 to promote clarity and amended claims 21 and 26 to include all limitations of amended claim 2. Further, Applicants have cancelled claim 27. Note that claims 1, 7-9, 12, 14, 19, 20, and 39 were previously canceled.

Upon entry of the present amendments, claims 2-6, 10, 11, 13, 15-18, 21-26, 28-38, and 40-45 will be pending. Among them, claims 17, 18, 21-26, 28-38, and 40-45 have been withdrawn from consideration and claims 2-6, 10, 11, 13, 15, and 16 are under examination.

All of the claims under examination are rejected on the ground that they are anticipated by Yamaoka et al, 1998, Infection and Immunity, vol. 66:5020-5026 ("Yamaoka"). See the Office Action, pages 2-4.

Claim 2, as previously presented, will be discussed first. This claim covers a conjugate containing a mutated superantigen coupled to an antigen. It requires that the mutated superantigen contain one or more mutations only in its T-cell binding site as compared to its wild-type counterpart. It further requires that the claimed conjugate be effective in antigen presentation.[1]

During the telephone interview on April 24, 2009, Applicants' counsel pointed out that, as the present specification is concerned about use of **superantigen** mutants to promote immunogenicity, it is clear to a skilled person in the art, in view of the

[1] Applicants proposed to amend claim 2 by incorporating a phrase "the conjugate binds to a Class II MHC molecule" in their response to the Office Action dated October 26, 2006, which was co-filed on June 22, 2007 with a Request for Continued Examination. The Examiner contended that this proposed amendment constituted new matter and denied its entry. See the Office Action dated August 27, 2007, page 5 and the Office Action dated May 12, 2008, page 5. In response, Applicants proposed in their reply to the Office Action dated May 12, 2008 to replace the amendment at issue with "the conjugate is effective in antigen presentation," a phrase that has literal support in the specification.

specification, that the conjugate of previously presented claim 2, containing a **superantigen** mutant, is effective in **superantigen** presentation, thereby promoting immunogenecity. Applicants' counsel further brought to the Examiner's attention a teaching provided in Abbas et al., Cellular and Molecular Immunology, page 347 (copy attached as Exhibit 1), a well-recognized immunology textbook, that relates to **superantigen** presentation. According to Abbas et al., a **superantigen** binds to a class II MHC molecule on an antigen-presenting cell via its MHC-binding domain and, consequently, is presented by the antigen-presenting cell to activate T cells. In view of this teaching, a skilled person in the art would have readily known that **binding to a class II MHC molecule** is a prerequisite for **superantigen** presentation.

During the interview, Applicants' counsel reiterated that, for the reasons set forth in Applicants' response to the Office Action dated April 24, 2006, filed on August 24, 2006 ("Response"), Yamaoka discloses GST-superantigen fusion proteins that are **NOT capable of binding to a class II MHC molecule** and therefore are **ineffective** in **superantigen** presentation. For the Examiner's convenience, Applicants reproduce these reasons below:

Yamaoka discloses GST-fusion superantigen mutants, in which the GST portion is fused to the N-terminal of each of the superantigen mutants. See page 5021, left column. It is known in the art that the N-terminal region of a superantigen is critical for its binding to a Class II MHC molecule. See Yamaoka, page 5021, right column. Accordingly, a peptide fused to the N-terminal of a superantigen would interfere with its binding to a Class II MHC molecule. Indeed, Applicants' own experimental data clearly demonstrate that pigeon cytochrome C peptide, when fused to the N-terminal of SPE-C, a superantigen, prevents SPE-C from binding to MHC Class II molecules. See Exhibit A co-filed with the Response. According to these teachings, a skilled person in the art would have readily recognized that the GST-fusion superantigen mutants disclosed in Yamoaka would not bind to a Class II MHC molecule.

After considering the facts and arguments presented by Applicants' counsel in the interview, the Examiner agreed that the conjugate of previously presented claim 2 is

different from the GST-superantigen fusion proteins disclosed in Yamaoka. For the sake of clarity, she requested that Applicants replace the phrase "effective in antigen presentation" recited in previously presented claim 2 with the phrase "capable of binding to a class II MHC molecule" and explicitly indicated that she no longer deemed this replacement phrase as constituting new matter.

For the sole purpose of accelerating prosecution, Applicants have amended claim 2 in the manner suggested by the Examiner. It is respectfully submitted that amended claim 2 is novel over Yamaoka. So are claims 3-6, 10, 11, 13, 15, and 16, all of which depend from claim 2.

## CONCLUSION

In view of the above remarks, Applicants submit that this application is now in condition for allowance. Favorable consideration is therefore respectfully solicited.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The Petition for Extension of Time fee in the amount of $ 245 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account

authorization. Please apply any other charges to Deposit Account No. 50-4189, referencing Attorney Docket No. 55503-002001.

Respectfully submitted,

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